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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/306,986

05/07/1999

THUAN QUOC TRINH

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

07/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/306,986	Applicant(s) TRINH ET AL.	
	Examiner Richard G. Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13,56 and 70-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13,56 and 70-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/30/2010 has been entered.

Applicant's amendment of claims 8, in the paper of 4/30/2010 is acknowledged.

Claims 8-13, 56 and 70-75 remain at issue and are present for examination. Applicant's review of the case history of the present application is also acknowledged and appreciated. Applicants' arguments filed on 4/30/2010, have been fully considered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-13, 56, 70-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Maudru et al. (Journal of Virological Methods 66: 247-261, July 1997).

This rejection was stated in the previous office action as it applied to previous claims 8-13, 56, 70-75. In response to this rejection applicants have amended claim 8 and traverse the rejection as it applies to the newly amended claim.

As previously stated, Maudru discloses the method of the claimed invention at page 250, beginning in the bottom of column 1 in the section entitled "2.2.2.

Polymerase chain reaction (PCR)". This section describes conduction of PCR in the presence of both RNase and thermostable DNA polymerase. Thus Maudru describes a step of "a) mixing the preparation with one or more DNA polymerases, and one or more peptides or polypeptides having ribonuclease activity, wherein said peptides or polypeptides having ribonuclease activity are capable of degrading single-stranded RNA," as claimed. The preparation of Maudru et al. is considered a crude preparation as applicant's specification states that: "The composition is especially useful in DNA synthesis when the sample is crude, i.e. prepared rapidly such that it contains contaminating RNA". Because Maudru conducts PCR using a double stranded DNA, Maudru discloses a step of "b) incubating said mixture under conditions sufficient to synthesize a nucleic acid molecule complementary to all or a portion of said double-stranded DNA and under which said peptides or polypeptides having ribonuclease activity degrade said single-stranded RNA," as claimed. Maudru section 2.2.2. further describes conducting RNase digestion for 30 minutes prior to conducting PCR for 35 cycles and the inclusion of buffers and nucleotides. This procedure is conducted to reduce background signals caused by an intrinsic RNA-dependent DNA polymerase activity of the thermostable Taq DNA polymerase, the enzyme used in PCR. (Maudru,

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abstract.). It is noted that while Maudru et al. do not necessarily teach that said methods include a detectably labeled nucleotide, claim 13 is drawn to the method of claim 10 which is drawn to the inclusion of such detectably labeled nucleotide in the alternative. Further claims 70-75 are included in the rejection because claims 70-75 appear to specify the "conditions sufficient to synthesize " a specific type of double stranded DNA. As the "conditions sufficient to synthesize " taught by Maudru et al. are sufficient to synthesize each of the various double stranded DNAs recited in claims 70-75, these claims are included in the rejection.

Applicants traverse this rejection on the basis that applicants submit that Maudru does not teach a method that includes all of the steps encompassed by the currently presented claims. Applicants submit that in particular, Maudru does not teach a step whereby ribonuclease treatment occurs simultaneously with nucleic acid synthesis. Applicants submit that, thus, Maudru does not teach the present claims and, for at least this reason, Applicants respectfully request that the rejection of claims 8-13, 56 and 70-75 under 35 U.S.C. § 102(b) as being anticipated by Maudru, *et al.* be withdrawn accordingly.

Applicant's complete amendment of the claims and applicants complete traversal is acknowledged and has been carefully considered, however, is not found persuasive for the reasons previously stated and for those reasons repeated herein.

With regard to applicant's submission that Maudru does not teach a step whereby "ribonuclease treatment" occurs "simultaneously with nucleic acid synthesis", it

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is unclear where such a limitation occurs in the claimed method. The examiner assumes that applicants are referring to part "b)" of claim 8 which after applicant's amendment states:

b) incubating said mixture under conditions sufficient to synthesize a nucleic acid molecule complementary to all or a portion of said double-stranded DNA and under which said peptides or polypeptides having ribonuclease activity simultaneously degrade said single-stranded RNA.

Applicants claimed method states "incubating said mixture under conditions" and then goes on to define the "conditions under which said mixture is incubated. The referred to conditions are 1) those sufficient to synthesize a nucleic acid molecule complementary to all or a portion of said double-stranded DNA and 2) under which said peptides or polypeptides having ribonuclease activity simultaneously degrade said single-stranded RNA. Madru et al. meets the limitation of part b) of claim 8, as Maudru et al. "incubate said mixture under the required conditions. That is Madru et al. incubates the taught mixture under conditions which are 1) those sufficient to synthesize a nucleic acid molecule complementary to all or a portion of said double-stranded DNA and 2) under which said peptides or polypeptides having ribonuclease activity simultaneously degrade said single-stranded RNA.

The claimed method only requires that the mixture be incubated under the referred to conditions, not that "ribonuclease treatment" occurs "simultaneously with nucleic acid synthesis". For these reasons applicants amendment and argument are not persuasive in overcoming the rejection and Maudru continues to anticipate claims 8-13, 56, 70-75.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mondesi Robert can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rgH
7/2/2010

/Richard G Hutson/
Primary Examiner, Art Unit 1652